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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,996	09/02/2003	Kyu-Hang Kyung	58333/117	1422
22428	7590	06/08/2005		EXAMINER
FOLEY AND LARDNER				FLOOD, MICHELE C
SUITE 500				
3000 K STREET NW			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20007				1654

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/651,996	KYUNG, KYU-HANG	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite and incomplete because the claim fails to provide a recovery step of the claim-designated product, namely "a natural preservative". For instance, the claim recites a method for preparing a natural preservative comprising the claim-designated process steps of a), b), and c), however, nowhere in the claim does Applicant provide a recovery step of "a natural preservative". Instead, the claim only provides an inactivation step to obtain alliinase-inactivated garlic; an extraction step of the alliinase-inactivated garlic to obtain garlic extract; and a heating step of the garlic extract. Please note that for the purposes of examination and for expediting prosecution of the present application, the Office assumes that the heated garlic extract is the claim-designated product of "a natural preservative".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kominato et al. (N, Translation of foreign patent document provided herein.).

Applicant claims a method for preparing a natural preservative comprising: a) inactivating alliinase contained in garlic to obtain alliinase-inactivated garlic; b) extracting said alliinase-inactivated garlic to obtain garlic extract; and c) heating said garlic extract. Applicant further claims a natural preservative which is prepared by the method according to any one of claims 1 to 6.

Kominato teaches a method for preparing a natural preservative comprising the instantly claimed process steps. For instance, Kominato teaches preparing a garlic extract by heating garlic flakes and simultaneously grinding the heated garlic flakes. Kominato further teaches that the garlic extract is obtained by deactivating enzymes contained in garlic, extracting the treated garlic with ethanol, subjecting the extract to an adsorption and a desorption treatment, powdering the treated extract, and subsequently heating the powdered extract. See abstract. In [0021] of the translation, Kominato teaches that the garlic extract contains many allyl sulfide compounds; and, in [0029], Kominato further teaches heating the garlic extract at 90-105°C.

Kominato does not teach the method of making the reference composition as a method for preparing a natural preservative. However, the method of making the composition taught by Kominato comprises the same ingredients and the same process steps, as instantly claimed by Applicant. Therefore, the method of making the garlic extract taught by Kominato inherently encompasses a method for preparing a natural preservative; and, a product thereof.

Please note that "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

The reference anticipates the claimed subject matter.

Claims 1-7 are rejected under 35 U.S.C. 102(b) or at least a) as being anticipated by Kyung et al. (U).

Applicant's claimed invention of Claims 1 and 7 was set forth above. Applicant further claims the method according to claim 1, wherein said step a) is heating garlic in water at 90°C to 100°C for 5 minutes to 15 minutes; wherein said step b) is crushing

and centrifuging said alliinase-inactivated garlic to obtain garlic extract; wherein said step c) is heating said garlic extract at 100°C to 190°C for 10 minutes to 10 hours; wherein said step c) is heating said garlic extract at 110°C to 140°C for 15 minutes to 180 minutes; and, wherein said step c) is heating said garlic extract at 121°C for 45 minutes.

Kyung teaches a method for preparing a natural preservative comprising inactivating alliinase contained in garlic to obtain alliinase-inactivated garlic by boiling garlic cloves in water for 5 minutes; crushing the alliinase-inactivated garlic in water in a blender and centrifuging to obtain a supernatant comprising a garlic extract; and heating the garlic extract at 121°C for different periods of time (0 to 120 minutes) at 15 minute intervals, including an interval of 45 minutes. Page 781, Column 1, under "*Preparation of heated garlic extract*"; and, Figure 1 and Figure 2. The composition produced by the method taught by Kyung exhibited bacteriostatic activity.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kominato et al. (N) in view of Uchiyama et al. (O, Translation of foreign patent document provided herein.).

Applicant's claimed invention was set forth above.

The teachings of Kominato are set forth above. Kominato teaches the instantly claimed method except for wherein said step a) is heating garlic in water at 90°C to 100°C for 5 minutes to 15 minutes; and, wherein said step b) is crushing and centrifuging said alliinase-inactivated garlic to obtain garlic extract. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed process steps and experimental parameters to the method of making the product taught by Kominato to provide the instantly claimed method for preparing a natural preservative because at the time the invention was made the instantly claimed process steps and experimental parameters were known in the art as conventional process steps for obtaining an alliinase-inactivated garlic extract. For instance, Uchiyama teaches a method of heat-treating garlic in water so as to deactivate the alliinase contained in the garlic at 80-100°C for 10-30 minutes to obtain alliinase-inactivated garlic, in [0010] of the translated document. In [0011], Uchiyama teaches, "Subsequently, the heat-treated raw material garlic is crushed, water is added, alliin is extracted, and it [is] considered as a garlic crude extract. A high performance mixer, a homogenizer, etc., are suitably used for crushing of this garlic." Uchiyama further teaches, "A part for an insoluble fiber etc, is contained in the crushed garlic, and the liquid which added water and was stirred to the debris of a heat treatment garlic removes an insoluble element according to

filtration or centrifugal separation." At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have been motivated to modify the method taught by Kominato by adding the instantly claimed process steps and experimental parameters to the method of making the product taught by Kominato to provide the instantly claimed method because Uchiyama teaches heating garlic in water at the claim-designated experimental parameters of temperature range and time range are beneficial in deactivating alliinase contained in garlic; and, crushing and centrifuging alliinase-inactivated garlic extract is useful as an extraction process step for obtaining a garlic extract.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (V) or Yu et al. (W) or Kubec et al. (X) in view of Uchiyama et al. (O), and further in view of Small et al. (A10, Small, L. D. et al., JACS (1947), 69: 1710-1713. *Alkyl Thiosulfinates*.) and Sanick (P).

Applicant's claimed invention was set forth above.

Each of Yu (V), Yu (W) and Kubec teaches a method for preparing alkyl thiosulfates, which are known in the art as bacteriostatic/preservative agents as evidenced by the teachings of Small and Sanick, by heating alliin or deoxyalliin in an aqueous solution. For instance, Yu (V) teaches a method for the thermal decomposition

of alliin or deoxyalliin dissolved in water comprising adjusting the solution to either a pH of 3, 5 or 7 and heating at 180°C in an oven for 1 hour to obtain a decomposed alliin or deoxyalliin, on page 146, Column 2, under "*Thermal Decomposition of Alliin and Deoxyalliin*". On page 146, in Table 2 and on page 147, in Table 3, Yu further teaches identification of compounds, such as diallyl sulfide, from the thermally degraded deoxyalliin and alliin aqueous solutions, respectively. In another instance, Yu (W) teaches a method for the thermal decomposition of alliin or deoxyalliin dissolved in water comprising adjusting the solution to either a pH of 3, 5 or 7 and heating at 180°C in an oven for 1 hour to obtain a decomposed alliin aqueous solution, wherein compounds such as methyl allyldisulfide and 3,5-dimethyl-1,2,4-trithiolane, were identified. Kubec also teaches a method for the thermal degradation of alliin and deoxyalliin comprising heating treating the compounds in an aqueous solution at 120°C to 180°C for 1 hour to obtain diallyl mono, di, and trisulfides. For example, in Table 1 on page 3581, Kubec teaches identifying compounds, such as diallyl sulfide, diallyl disulfide, 2-vinyl-1,3-dithane and diallyl trisulfide, from thermally degraded alliin. Similar compounds were found in the thermally degraded deoxyalliin, as set forth in Table 2, on page 3582.

Each of the individual teachings of Yu (V or W) and Kubec are set forth above. Neither Yu (V or W) nor Kubec teach a method for preparing the antibacterial preservative thiosulfates wherein the allicin and/or deoxyalliin are obtained by the claim-designated method steps of Claim 1 and Claim 3. However, it would have been obvious to one of ordinary skill in the art to modify the methods taught by Yu (V) or Yu

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(W) or Kubec by adding the claim-designated process steps of a) inactivating alliinase contained in garlic to obtain alliinase-inactivated garlic and b) extracting said alliinase-inactivated garlic to obtain garlic extract and the claim-designated process step wherein b) is crushing and centrifuging said alliinase-inactivated garlic to obtain garlic extract step because at the time the invention was made Uchiyama taught that garlic extract containing allicin could be extracted from garlic comprising the instantly claimed process. For instance, Uchiyama teaches a method of heat-treating garlic in water so as to deactivate the alliinase contained in the garlic at 80-100°C for 10-30 minutes to obtain alliinase-inactivated garlic, in [0010] of the translated document. In [0011], Uchiyama teaches, "Subsequently, the heat-treated raw material garlic is crushed, water is added, alliin is extracted, and it [is] considered as a garlic crude extract. A high performance mixer, a homogenizer, etc., are suitably used for crushing of this garlic." Uchiyama further teaches, "A part for an insoluble fiber etc, is contained in the crushed garlic, and the liquid which added water and was stirred to the debris of a heat treatment garlic removes an insoluble element according to filtration or centrifugal separation." At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to modify any of the methods for the thermal degradation of allicin and/or deoxyalliin taught by Yu (V or W) and Kubec by adding the instantly claimed process steps for processing garlic to provide the instantly claimed method of making a natural preservative and a product thereof because Uchiyama taught heating garlic in water at the claim-designated experimental parameters of temperature range and time range are

beneficial in deactivating alliinase contained in garlic; and, that crushing and centrifuging alliinase-inactivated garlic extract is useful as an extraction process step for obtaining a garlic extract containing alliin therein; and, Yu (V or W) and Kubec each taught that garlic is good source of alliin; for example, Yu (W) teaches, "It is also well-known that that the enzyme allinase, which is activated when the cellular tissue of garlic is disrupted, converts alliin to allicin [citation omitted]. Boiling the garlic bulb or homogenizing the garlic bulb with alcohol containing limited amounts of water deactivates the enzyme; alliin is not converted to allicin and no pungent odor can be detected from the garlic samples." and, each of Yu (V or W) and Kubec taught that thermal decomposition of alliin in aqueous solutions is useful in the making of alkyl thiosulfinates, such as allyl disulfide, known in the art as having a preservative effect due to their anti-bacterial and anti-fungal activities, as evidenced by the teachings of Small and Sanick. Thus, the instantly claimed method is no more than the replacement of one source of alliin for another, since the prior art teaches that inactivation of alliinase contained in garlic to obtain alliinase-inactivated garlic extract can be done by briefly boiling garlic in water; and that extraction of alliinase-inactivated to obtain a garlic extract containing alliin can be done by crushing and centrifuging alliinase-inactivated garlic extract to obtain a garlic extract containing alliin which can be thermally decomposed to provide for the making of compounds having a preservative effect, and a product thereof from a natural source, such as garlic.

As each of the references indicate that the ingredients, process steps and experimental parameters used in the claimed method for preparing a natural

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preservative from garlic are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**MICHELE FLOOD
PRIMARY EXAMINER**

Michele C. Flood
MCF

June 6, 2005